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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/718,976	11/20/2003	Syed F.A. Hossainy	50623.317	2726

7590 03/26/2007
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EXAMINER

ROGERS, JAMES WILLIAM

ART UNIT	PAPER NUMBER
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1618

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	03/26/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No. 10/718,976	Applicant(s) HOSSAINY ET AL.	
	Examiner James W. Rogers, Ph.D.	Art Unit 1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 November 2003.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-36 is/are pending in the application.
- 4a) Of the above claim(s) 13, 14, 31 and 32 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-12, 15-30 and 33-36 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☒ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>06/13/2005</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

This application contains claims directed to the following patentably distinct species: The various triblock copolymers in claims 11,13,29 and 31. The species are independent or distinct because the triblock copolymers are materially different in that they do not have the same sequence of blocks (PLA-PEG-PLA and PEO-PLA-PEO), thus the triblock copolymers would have materially different properties and a search for one species would not necessarily result in a full search for the other copolymer. This would put an undue burden on the examiner in regards to search purposes and thus an election of species is deemed necessary.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 11,13,29 and 31 are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after

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the election, applicant must indicate which are readable upon the elected species.

MPEP § 809.02(a).

During a telephone conversation with CAMERON KERRIGAN, the attorney of record for application number 10/718,976 on 3/8/2007 a provisional election was made without traverse to prosecute the species of triblock copolymers recited in claims 11 and 29. Affirmation of this election must be made by applicant in replying to this Office action. Claims 13-14 and 31-32 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 4,15,22 and 33 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Specifically the claims recite a limitation in which the di-block or tri-block copolymers are hydrolyzed, there is inadequate written support within the specification for these limitations. The specification recites that the block copolymers can be hydrolyzed under conditions that

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can be selected by those of ordinary skill in the art. See [0057] of US Pub 2005/0112170. This recitation does not adequately describe how the hydrolysis is performed or the expected results; there is insufficient information within the specification to produce the claimed hydrolyzed block copolymers. Applicants have not shown at the time of the invention that they had possession of the invention recited in claims 15 and 33.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 1-12, 15-21, 23-30 and 34-36 are rejected under 35 U.S.C. 102(b) as being anticipated by Yang et al. (US 6,258,121 B1, disclosed by applicants).

Yang teaches a stent having a polymeric coating for controllably releasing an included active agent, the coating comprises polymeric materials and blends thereof selected from polymers such as polycaprolactone (PCL), polyhydroxybutyrate (PHB), poly(lactide-co-glycolide) and preferably PLA-PEO copolymer for example. See abstract, col 4 lin 4-22. Regarding the limitation that the PLA-PEO copolymer is a triblock, Yang incorporates by reference the PLA-PEO copolymers of Kim et al (US 5,548,035) who teaches the use of PLA-PEO-PLA blocks. See col 5 lin 5-7. Kim's copolymers also meet applicants claimed integer range for n and m in claims 10,12,28 and 30. Regarding claims 4 and 15 the limitation that the di-block or tri-block copolymers are hydrolyzed does not give the claim any patentable distinction from Yang. By further processing the copolymers by hydrolysis applicants are essentially shortening the PLA segments by degrading them, therefore the copolymers will essentially have a range of different sized PLA units. This is not seen as being patentably distinct from Yang's copolymers synthesized by coupling PEG to PLA, in which PLA if synthesized or purchased from a commercial source will have numerous lengths with varying molecular weights, therefore the additional treatment claimed by applicants does not give the claim any patentable distinction from the Yang reference. Both methods to make the copolymer would essentially result in PLA blocks of varying lengths, therefore the claimed invention is the same because the claims are to a medical article not the method to polymerize the coating.

Claims 1-9,15-27 and 34-36 are rejected under 35 U.S.C. 102(e) as being anticipated by Schwarz et al. (US 2003/0203000 A1).

Schwarz teaches therapeutic-agent-loaded polymeric carriers that can be used as medical device coatings such as stents, the polymeric carrier can comprise a blend of polymers such as PEO-PLA copolymer, PCL, PHB and polyhydrovalerate for example. See [0009], [0016]-[0018],[0028],[0031]-[0032]. Regarding claims 4 and 15 the arguments from above are incorporated herein as well.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-12,15-30 and 33-36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yang et al. (US 6,258,121 B1, disclosed by applicants) in view of Okada et al. (US 6,113,943).

Yang is disclosed above.

Yang does not disclose a hydrolyzing treatment of the PEO-PLA copolymers to be incorporated into the stent coating.

Okada is used only for the disclosure within that it was advantageous to hydrolyze a polylactic acid for sustained release preparations. The disclosed advantage was that the hydrolyzed lactic acid provided a sustained release preparation with a small initial burst of active ingredient, this is in contrast to polylactic acid formed from ring-opening polymerization in which the sustained release provided a large initial burst. The skilled artisan could foresee from the disclosures of Yang and Okada that PLA-PEG-PLA copolymers would also be susceptible to a hydrolyzing step, this is obviously so because PLA block is the same and the PEG block would not undergo hydrolysis because only the outer shell (PLA) of the copolymer will undergo hydrolysis, thus only the PLA portion of the block would be effected by the treatment.

It would have been prime facie obvious to a person of ordinary skill in the art at the time the claimed invention was made to combine the art described in the documents above because Yang discloses all of applicants claimed invention except a hydrolyzing treatment processing step of the PEO-PLA copolymers to be incorporated into the stent coating, while Okada disclosed hydrolyzed PLA was already known in the art at the time of the invention. The motivation to combine the above documents would be to provide a coated stent with a block copolymer comprising hydrolyzed PLA that would provide a sustained release of a bioactive agent. The advantage of such a stent coating would be that the hydrolyzed lactic acid would provide a sustained release with a small initial

burst of active ingredient. Thus, the claimed invention, taken as a whole was *prima facie* obvious over the combined teachings of the prior art.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-9,11,15,18,19-21,23-27,29 and 36 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-19 of U.S. Patent No. 7,169,404 B1. Although the conflicting claims are not identical, they are not patentably distinct from each other because both claim a stent coating comprising a di-block or tri-block copolymer comprised of PLA and PEG and an active agent.

Claims 1-12,15-21,23-30 and 34-36 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims

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1,17,24-26,37,68-78 of copending Application No. 10/925257. Although the conflicting claims are not identical, they are not patentably distinct from each other because both claim a stent coating comprising a di-block or tri-block copolymer comprised of PLA and PEG blended with other polymers such as PCL and an active agent.

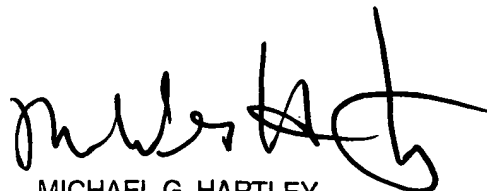
This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

No claims are allowed. Any inquiry concerning this communication or earlier communications from the examiner should be directed to James W. Rogers, Ph.D. whose telephone number is (571) 272-7838. The examiner can normally be reached on 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



MICHAEL G. HARTLEY
SUPERVISORY PATENT EXAMINER